

REMARKS

Applicant submits this Amendment following the Final Rejection of May 1, 2002, the Notice of Appeal filed by Applicant on July 25, 2002, the Appeal Brief filed by Applicant on September 24, 2002, the Examiner's Answer of November 12, 2002, and the Reply Brief from the Applicant on January 13, 2003. Applicant submits with this Amendment a Request for Continued Prosecution of this application according to 37 C.F.R. §1.114 and the required fees according to 37 C.F.R. §1.17(e).

All claims pending at the time of the Final Rejection, claims 75 to 82, remain pending in the application. New claims 83 to 89 have been added. Support in the specification for the new claims is as follows. Support for claim 83 is found on page 4, lines 3 to 14. Support for claim 84 is found on page 4, line 15. Support for claim 85 is found on page 4, line 16. Support for claim 86 is found on page 4, lines 24-26. Support for claim 87 is found on throughout the specification, for example at page 6, lines 30 to 36. Support for claim 88 is found on page 6, line 10. Support for claim 89 is found on page 6, line 14.

REJECTIONS OF THE CLAIMS

Rejection under 35 U.S.C. §103(a)

The Examiner has rejected claims 75 to 82 as being obvious under 35 U.S.C. §103(a) over Embleton et al (WO 97/23177) in view of Laibovitz et al (U.S. Patent No. 5,997,518). Applicant traverses the rejection of the claims on this ground.

Embleton discloses an apparatus for delivering small volumes of liquid to the eye in the form of a jet or stream of droplets. The apparatus of Embleton provides a minimum range of

volume of treatment fluid to be between 3 to 8 microliters. Embleton further discloses that the ophthalmic treatment liquids that may be used with the invention include:

- 6) Artificial tear/dry eye therapies, comfort drops, irrigation fluids, etc., e.g. physiological saline, water, or oils; all optionally containing polymeric compounds such as acetylcysteine, hydroxyethylcellulose, hydroxymellose, hyaluronic acid, polyvinyl alcohol, polyacrylic acid derivatives, etc. (page 13, lines 6-12)

Laibovitz discloses an apparatus for delivering small volumes of liquid to the eye in the form of very small droplets. The invention of Laibovitz overcomes the adhesion forces that are encountered when delivering drops of liquid to the eye from droppers, such as surface tension at the tip diameter, difficulties in use, lack of control of quantity, and contamination. Laibovitz discloses that this apparatus can deliver small volumes which permits the efficient use of therapeutic medications because administration of small volumes prevents runoff of the medications with resultant wastage of medication or loss of medication into the tear duct with subsequent inhalation and entry into the systemic circulation. The device of Labovitz can deliver drops in the size of those in an aerosol or mist. See column 11, lines 32-34.

A. The Examiner has failed to establish a *prima facie* case of obviousness

Applicant submits that the prior art, either alone or in combination, does not disclose or suggest the present invention as called for in independent claim 75 and claims dependent therefrom. Moreover, as discussed below neither Embleton or Laibovitz disclose or suggest the present invention of a method for moisturizing the surface of the eye by administering an aqueous formulation in the form of a mist.

Applicant submits that it is error to combine the disclosure of Embleton and Laibovitz to reject claims drawn to a mist as (1) Embleton teaches away from a mist and (2) Laibovitz likewise teaches away from a mist.

As discussed previously in connection with this application, Embleton discloses a jet or stream of droplets. The Examiner has stated several times during the prosecution of this application that there is no difference between a jet or stream of droplets and a mist. In the words of the Examiner:

The examiner does not recognize a distinction between mist,
multiplicity of droplets, dispersed droplets in air, stream of
droplets, or a cloud-like aggregation of minute globules in air.

However, Applicant respectfully submits that the Examiner is in error. Applicant has previously provided dictionary definitions that establish that jets and streams are distinct from mists. Moreover, Applicant respectfully submits that, although Laibovitz discloses that his apparatus may emit droplets the size of those found in a mist, Laibovitz, like Embleton, also teaches away from a mist.

As stated in Laibovitz at column 14, lines 20 to 25, in reference to mists:

Moreover the spray pattern of a perfume atomizer is generally
greater than about two (2) inches in diameter and is therefore
unsuitable for the preferred prime uses of the apparatuses of the
invention which are for controlled application of extremely small
quantities of drugs to the eye in less than two inch diameter
patterns.

The teaching away from a mist in Laibovitz has not previously been discussed in reference to this application by either the Examiner or Applicant. It is clear that, although the Examiner fails to recognize a distinction between a mist and a jet or a stream, those skilled in the relevant art of administering liquids to the eye do indeed recognize such a distinction and both of the cited references teach away from the use of a mist.

Even without reference to the claimed mist, Applicant submits that neither Embleton, Laibovitz, or the combination of Embleton and Laibovitz disclose or suggest the present invention. Both Embleton and Laibovitz deal with the problem of overdosing a liquid containing a medicament to the eye. Such overdosing results in two deleterious effects. The first such deleterious effect is that providing a medicament in an amount of liquid that is greater than that which can be retained by the eye results in wastage of the medicament and a lack of precision in dosage. The second and more serious deleterious defect is that providing a medicament in a too large volume of fluid to the eye results in runoff of the medicament down the tear duct and into the nasal passages where it can be inhaled into the systemic circulation of a patient, with potentially disastrous effects depending on the nature of the medicament.

Neither Embleton or Laibovitz deal with the problem of moisturizing the surface of the eye and one skilled in the art, upon reading Embleton and Laibovitz, would not understand that the quantities of fluid disclosed and claimed in the present invention, are sufficient for moisturizing the eye. Thus, the prior art does not disclose or suggest the present invention.

For these reasons, it is asserted by Applicant that the Examiner has failed to establish a *prima facie* case of obviousness of the claims in view of the prior art. The references fail to disclose or suggest the present invention to moisturize the surface of the eye utilizing the

amounts of fluid called for in the claims and and, in fact, the prior art teaches away from one of the embodiments of the invention, namely a mist. Accordingly, Applicant respectfully requests the Examiner to withdraw the rejection of the claims on this ground.

B. Even if a prima facie case of obviousness has been made, the rejection is rebutted

Applicant submits that, even if the Examiner maintains that he has established a prima facie case of obviousness, with which Applicant respectfully disagrees, the prima facie case of obviousness is successfully rebutted following an examination of the following evidence, each of which is co-filed with this Amendment and is discussed in detail below.

1. Declaration of Dr. Philip Paden with compact disc
2. Declaration of Dr. Darwin Liao
3. Declaration of Dr. William Mathers
4. Exchange & Commissary News, 43(1):6 (January 15, 2004)

1. Declaration of Dr. Philip Paden

Dr. Philip Paden, an ophthalmologic surgeon, has submitted a Declaration, co-filed with this Amendment, in which he testifies that the use of an aqueous fluid consisting essentially of water to moisturize the surface of the eye, as is presently called for in the appealed claims 75 to 82, represents a significant departure from previous accepted doctrine in ophthalmology. Applicant submits that such a departure from established dogma establishes that the presently claimed invention is not obvious in view of the present art.

Moreover, with his Declaration, Dr. Paden has submitted a 3-minute long CD disc entitled "Bio-Logic Aqua Technologies" that diagrammatically shows how the invention, when

practiced by application of a mist, restores the osmolarity of a tear film in a person suffering from dry eye to a comfortable physiologic level, and how such a mist may be used to moisten the eye using water, in contrast to previously accepted ophthalmologic dogma.

Applicant submits that Dr. Paden's Declaration provides evidence that establishes that the claimed invention is patentably distinct over the prior art. As stated in MPEP §2145 (X)(D)(3), "Proceeding Contrary to Accepted Wisdom is Evidence of Nonobviousness."

In view of Dr. Paden's Declaration, Applicant submits that the rejection of the claimed method of the invention as being obvious is overcome and requests the Examiner to withdraw this ground of rejection of the claims.

2. Declaration of Dr. Darwin J. Liao

Dr. Darwin J. Liao, an ophthalmologist, has submitted a Declaration, co-filed with this Amendment, in which he testifies that when he previously treated patients for "dry eye" with previously available methods, that is with eye drops, his patients often complained about eye drops. Dr. Liao's patients complained because eye drops are difficult to use and because they often make the eyes of a patient with dry eye feel worse.

Dr. Liao testified in the Declaration that he now uses a product called "Nature's Tears", which product is an embodiment of the present invention. Dr. Liao testified that he now uses this product as his primary choice for his dry eye patients because he no longer has problems with patient lack of compliance. His patients have commented that the product is easy to use and makes their dry eyes feel good. Dr. Liao further testified that he also uses this product to treat his own symptoms of dry eye as it is "far more effective in relieving my discomfort due to dry eye than are eye drops."

Applicant submits that Dr. Liao's Declaration establishes unexpected advantageous properties of the present invention over the prior art. The invention provides an ease of use unknown with previous ophthalmic therapies and increases patient compliance in patients suffering from symptoms of dry eye. Accordingly, Applicant submits that the Declaration of Dr. Liao establishes the non-obviousness of the present invention over the prior art.

Thus, Applicant submits that, in view of the Declaration of Dr. Liao, the rejection of the claims as being obvious over the prior art is overcome and the Examiner is requested to withdraw this ground of rejection of the claims.

3. Declaration of Dr. William D. Mathers

Dr. William D. Mathers, a professor of ophthalmology at the respected Casey Eye Institute of Oregon Health and Science University, has submitted a Declaration in support of the patentability of the present invention, which Declaration is co-filed with this Amendment. As shown in his curriculum vitae that is submitted with the Declaration, Dr. Mathers has been a primary or co-investigator in many research projects that have received millions of dollars in Federal, university, and privately funded grants and contracts. A great many of these research projects have been in the field of dry eye. Dr. Mathers has also published about 70 scientific articles and has been an author of chapters in 16 books dealing with the eyes. This is in addition to the numerous scholarly abstracts and presentations given by Dr. Mathers over the course of many years at professional ophthalmologic meetings.

Dr. Mathers, in his Declaration, provides factual evidence that establishes that the self-administration of a mist by patients suffering from dry eye or other causes of ocular irritation provides more effective relief than do other available methods of moisturizing the eye, such as

with eye drops. Dr. Mathers further provides factual evidence that administration by a mist is found to be more convenient and that patients prefer using a mist and would buy such a mist.

Applicant submits that the evidence provided in the Declaration of Dr. Mathers establishes unexpected advantageous properties of the present invention, that is that a mist is more effective in reducing symptoms of ocular irritation than are other forms of administration of fluid to the eye. Applicant further submits that this evidence, especially when combined with evidence that the invention provides an easier mode of administration than does eye drops and that patients would buy such a product, establishes the patentability of the present invention.

Accordingly, Applicant submits that the rejection of the claims as being obvious in view of the prior art is overcome and the Examiner is requested to withdraw the rejection of the claims on this ground.

4. Exchange & Commissary News, 43(1):6 (January 15, 2004)

Applicant submits as an attachment to this Amendment, the January 15, 2004 issue of Exchange & Commissary News, vol. 6 (1), page 6. The Exchange & Commissary News is a trade journal that covers sales of goods and services to the United States military.

On page 6 of the January 15, 2004 issue, the journal reports on Major Pete Van Amburgh of the Georgia-based 221st Military Intelligence battalion deployed in Iraq concerning his troops' appreciation of Nature's Tears, a commercial embodiment of the invention. Major Van Amburgh states that:

The conditions in Kuwait/Iraq are hot, dusty, sandy and windy.

Nature's Tears was a great way to get all that out of our eyes.

Van Amburgh further states that the soldiers began misting each other and appreciated the results as evidenced by the fact that “the cases emptied in no time”. See the picture at the top of page 6, right column.

The article further states that the product (Nature’s Tears) is now sold in military commissaries and that family members of the troops have placed orders in order to resupply their loved ones with the product.

Applicant submits that this article, showing utilization of the invention by the U.S. military based in Iraq, further establishes that the invention, particularly as embodied in the form of a mist, provides benefits that are not available by products of the prior art and is further evidence of the non-obviousness of the present invention. Accordingly, Applicant respectfully requests the Examiner to withdraw the rejection of the claims on this ground.

Conclusion

Applicant submits that the Examiner has failed to establish a case of *prima facie* obviousness of the claims in view of the prior art. Applicant further submits that, even if the Examiner has established a case of *prima facie* obviousness of the claims in view of the prior art, the evidence submitted by Applicant with this Amendment is sufficient to establish patentability of the claimed invention.

Accordingly, Applicant respectfully requests the Examiner to withdraw the rejection of the claims for obviousness and to issue a notice of allowance of the claims.

Respectfully submitted,



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Attachments:

1. Declaration of Dr. Philip Paden with 3-minute CD entitled Bio-Logic Aqua Technologies
2. Declaration of Dr. Darwin J. Liao
3. Declaration of Dr. William D. Mathers
4. Exchange & Commissary News, 43(1):6 (January 15, 2004)
5. Request for Continued Examination (RCE)

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on January 30, 2004.

Dated: 1/30/04


Howard M. Eisenberg